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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/901,320	07/09/2001	Rosario Brancato	118.002US01	7767

7590 11/22/2002

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EXAMINER

SAUCIER, SANDRA E

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 11/22/2002

7

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.  
09/901,320

Applicant(s)

Brancato et al.

Examiner

Sandra Saucier

Art Unit

1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1)  Responsive to communication(s) filed on Oct 23, 2002

2a)  This action is FINAL.      2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle* 1035 C.D. 11; 453 O.G. 213.

### Disposition of Claims

4)  Claim(s) 1-13 and 24 is/are pending in the applica

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from considera

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1-13 and 24 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirem

### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.

2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a)  The translation of the foreign language provisional application has been received.

15)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

1)  Notice of References Cited (PTO-892)

4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)

5)  Notice of Informal Patent Application (PTO-152)

3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

6)  Other: \_\_\_\_\_

Art Unit: 1651

**DETAILED ACTION**

Claims 1-13 and 24 are pending and are considered on the merits.

***Claim Rejections – 35 USC § 112***

**INDEFINITE**

Claims 1-13 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The method claims have no active steps such as “applying a medicament comprising ...Q<sub>10</sub> to the cornea of the eye of the subject”, rather merely stipulate the “use”. The claims provide for the use of CoQ<sub>10</sub>, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

The method claims have no recipient of the the action such as, “A method for treating a subject having pathology of the anterior chamber of the eye or incidental or post-surgical trauma of the anterior chamber of the eye comprising: applying...”.

Claim 11 requires that the castor oil be modified, but fails to specify what the modification is. The word “modified” is not defined in the specification and is not a term of art with regard to chemical compounds.

***Claim Rejections – 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action: (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made

Art Unit: 1651

in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1–10 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/11242 [L].

The claims are directed to the use of CoQ<sub>10</sub> to prevent and treat pathologies of the eye. The claims do not require that the CoQ<sub>10</sub> be topically applied to the eye. The claims do not require that the eye be post-surgical, but rather can be read to require only the use of CoQ<sub>10</sub> to prevent damage from exposure to the sun. All eyes could benefit from this result. Therefore, because the claims are so indefinite, any use of CoQ<sub>10</sub>, orally administered or otherwise could prevent damage to the eye from exposure to the sun and any administration is considered to read upon the claims. Please note that claims 5–9 do not REQUIRE that the eye be post-surgical, only that if it were post-surgical, the surgery would be a LASIK type treatment, for example.

Claim 10 does not require that CoQ<sub>10</sub> be administered topically, only that the composition is a topical formulation.

The references are relied upon as explained below.

WO 1999/11242 teaches the administering of CoQ<sub>10</sub> intraocularly. The inherent result of this administration would reasonably be expected to be the same result as obtained by the claimed method since the claimed method only requires the use of CoQ<sub>10</sub> to prevent damage induced by the sun. Patients administered the composition of example 2, page 8, intraocularly (abstract) would obtain this benefit as an inherent result of the method. The claims require nothing more.

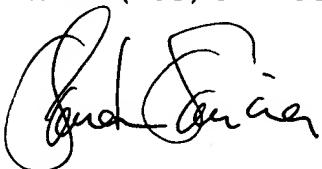
One of ordinary skill in the art would have been motivated at the time of invention to perform the claimed method as suggested by the reference with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Claims 11–13 appear to be free of the art.

Art Unit: 1651

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651. The supervisor for 1651 is M. Wityshyn, (703) 308-4743. The normal work schedule for Examiner Saucier is 8:30 AM to 5:00 PM Monday, Tuesday and 8:30 AM to noon on Wednesday.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (703) 308-1084. Status inquiries must be directed to the Customer Service Desk at (703) 308-0197 or (703)-308-0198. The number of the Fax Center for the faxing of official papers is (703) 872-9306 or for after finals (703) 872-9307.



Sandra Saucier  
Primary Examiner  
Art Unit 1651  
November 19, 2002